

certain antimicrobial substances in food contact applications. Historically, such substances were regulated by the Food and Drug Administration (FDA) as food additives and were approved by that agency under Section 409 of the (FFDCA). With the FQPA definitional changes, such substances now fall within the term "pesticide chemical" and are subject to regulation by the Environmental Protection Agency (EPA) under Section 408 of the FFDCA.

Since the passage of the FQPA in August 1996, these shifts in regulatory jurisdiction have led to delays in the processing of petitions for clearance of certain antimicrobials under the FFDCA. In the interim, in addition to the losses to the companies with pending petitions, the American public is losing the economic and environmental advantages that these products may offer. An amendment similar to the proposed technical correction was considered in October 1997, late in the conference on the FDA Modernization Act (FDAMA) but was deferred for later consideration. In the FDAMA Conference Report, however, the conferees urged the interested parties to pursue a new vehicle to achieve resolution of this jurisdictional issue.

The technical correction made by H.R. 4679 does not remove any use of a substance from regulation as a pesticide under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Thus, any use of an antimicrobial in the manufacture of packaging for both food and non-food applications that is a pesticidal use under FIFRA would, in addition to FDA review as a food additive, continue to be subject to pesticide registration under FIFRA. Moreover, the proposed legislative language does not affect FDA's existing jurisdiction over antimicrobial substances (with the exception of ethylene oxide and propylene oxide) used in or on processed food, which are not "pesticide chemicals" under the FFDCA.

H.R. 4679 would achieve the following:

1. Consistent with its traditional broad regulatory authority over food products and processing, FDA would have authority under FFDCA Section 409 to regulate as food additives—

Those antimicrobial substances used in or on food, or water that comes into contact with food, if such substances are used where food is prepared, packed or held for commercial purposes.

Most antimicrobials used as food contact substances, such as those used in the manufacture of food contact packaging.

2. Consistent with EPA's traditional role in reviewing uses of antimicrobials in agricultural applications, EPA would retain authority under FFDCA Section 408 to regulate—

Antimicrobials used on raw agricultural commodities, or on water used on such commodities in the field; in a facility where raw agricultural commodities are the only food treated, and the treatment is in a manner that does not change the status of the food as a raw agricultural commodity (e.g., washing, waxing, fumigating, and packing such commodities in such a manner); or during transportation of raw agricultural commodities between the field and such a treatment facility.

Under this legislation, Congress intends that EPA will continue to regulate fumigants applied to stored raw agricultural commodities in the above locations.

3. EPA would have regulatory authority under FFDCA, over residues of the fumigants

ethylene oxide and propylene oxide on both raw agricultural commodities and processed food, including ground spices. Additionally, use of ethylene oxide and propylene oxide on foods, including processed foods, will be a pesticidal use under FIFRA.

4. EPA would have regulatory authority over residues of antimicrobials used on semi-permanent or permanent food contact surfaces other than food packaging. Similarly, EPA would have regulatory authority over antimicrobial substances impregnated in semi-permanent or permanent food contact surfaces other than food packaging if the substance is intended to serve the same purpose as application of an antimicrobial to the exterior of such surface.

5. A "grandfather/transitional" provision would ensure that any regulation authorizing the use of an antimicrobial substance that, under this legislation is not a pesticide chemical use and thus is subject to FDA's regulatory authority under section 409, would be considered a regulation issued under Section 409. Thus, after the passage of the amendment, all antimicrobial products under FDA's food additive authority would be regulated under the same statutory authority.

Except as noted for ethylene oxide and propylene oxide, this amendment would affect the regulation of antimicrobial pesticides only under the FFDCA. EPA would continue to regulate antimicrobial pesticides under FIFRA, and EPA's authorities under that statute would not be changed. Companies selling or distributing antimicrobial pesticides must apply to EPA for registration of their products. EPA will review the applications under FIFRA sec. 3, which requires among other things that the products not cause "unreasonable adverse effects on the environment." That term is defined in FIFRA sec. 2(bb) to mean: "(1) any unreasonable adverse effects on the environment taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, and (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 408 of the Federal Food, Drug, and Cosmetic Act . . ."

Thus, it is Congress' intent that EPA, in deciding under FIFRA whether to grant, amend, or cancel a registration for an antimicrobial pesticide that poses a human dietary risk, shall take such action only if EPA determines that the risks from such residues are not inconsistent with the safety standard in FFDCA sec. 408. Additionally, Congress intends that in granting, modifying, or canceling a tolerance for a pesticide chemical residue under section 408, EPA consider exposures to substances regulated under section 409 where applicable.

Overall, the technical correction made by H.R. 4679 presents an opportunity to reverse a change that Congress did not intend to make and allow companies to bring these beneficial antimicrobial products to market without further unnecessary delay. Importantly, shifting regulatory jurisdiction over certain antimicrobial uses of FDA will continue to ensure public health protection provided by the FFDCA.

REGARDING LINDA BUSHELL

HON. SOLOMON P. ORTIZ

OF TEXAS

IN THE HOUSE OF REPRESENTATIVES

Tuesday, October 20, 1998

Mr. ORTIZ. Mr. Speaker, I rise to speak about and to congratulate a great teacher in my Congressional District, Linda Bushell. Linda Bushell, now an assistant principal at Martin Middle School in Corpus Christi, Texas, is being recognized for her work with students when she taught history at Baker Middle School from 1990–May 1998. She is being named to the All-USA Teacher Team, a representative of all outstanding teachers who daily work to open kids' minds and advance their knowledge. Nineteen individuals and one team of four, were selected from 649 nominees.

These exceptional teachers are being honored for making a difference. They inspire us not only as working professionals but also as citizens. Their extraordinary talent to connect with students and their ability to make learning fun enables them to reach out to kids and help them expand their horizons with special programs. Linda Bushell is one of four teachers who began the Community Connection program in Corpus Christi, Texas, a program to give at risk students an up-close look at why academics are relevant to real-world success. In this program Baker Middle School students volunteer at museums, hospitals, or other community sites, and observe professionals as well as hear them speak about what they do on a daily basis. These volunteer opportunities help inspire kids to be more than they believe they can be or do. For example, one young woman after volunteering at an office in the Nueces County courthouse stated happily, "I can really be a lawyer. Women can be lawyers." The program gives students self-confidence and gives them a view of the real world outside of what they daily experience in school.

Once again, I congratulate Linda Bushell for the superb job she does in the education arena for students in South Texas. We are fortunate to have teachers like you teaching our children. You deserve this recognition for you have given your heart and much hard worked hours for our students. Keep up the work.

THE BEST OF STAFF

HON. THOMAS J. MANTON

OF NEW YORK

IN THE HOUSE OF REPRESENTATIVES

Tuesday, October 20, 1998

Mr. MANTON. Mr. Speaker, I rise to pay tribute to my staff, both past and present, for their fine work, dedication, and loyalty.

Mr. Speaker, today, I likely cast my last vote as a Member of this august body. For fourteen years, I have served proudly my constituents of the 7th Congressional District of New York. I hope that I have served them well. I would be remiss, however, if I did not acknowledge and praise the hard-working men and woman who have served with me.

Congressional staff are all too often overlooked in their daily duties and under-appreciated for their efforts. But, as my colleagues well know, this great democratic institution